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March 29, 2024

VIA EMAIL and ECF

Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street
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Newark, New Jersey 07102

**Re: U.S. ex rel. Silbersher v. Janssen Biotech Inc.
Civil Action No. 19-12107(MEF-ESK)**

Dear Judge Arpert:

Pursuant to Judge Kiel's March 18, 2024 Order, the parties in the above-referenced matter respectfully submit this list of open discovery disputes, and identify where they were previously fully briefed by the parties:

I. Relator's Open Disputes

1. Defendants' refusal to conduct terms and connectors searches for key witnesses; produce documents in witnesses' personnel files disclosing, among other things, the identity of specific corporate employers and reporting responsibilities; and produce memoranda and draft articles of legal topics relevant to this litigation. ECF 330.
2. Relator intends to file a motion challenging Defendants' assertion of privilege. The parties will agree on a briefing schedule to follow after the deposition of Mr. Timothy Tracy (one of two lead patent attorneys) now scheduled for April 11, 2024.

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3. Defendants' deficient answers to Relator's Interrogatories.

- a. Interrogatory No. 9 requests Defendants to identify the date and participants of meetings or discussions where the allegedly fraudulent Commercial Success Argument was discussed or analyzed in connection with the prosecution of the patent. Defendants simply refer to their privilege log. ECF 302, at 2.
- b. Interrogatory No. 15 requests Defendants to "identify all persons and documents" that their internal patent prosecution attorneys consulted with or relied upon prior in advancing the Commercial Success Argument. In response, Defendants refer to various documents that were "produced from Ms. Kamage's files." ECF 302, at 2. Defendants do not specify which documents were actually relied upon; whether other documents not in Ms. Kamage's files were relied upon (such as those found in Mr. Tracy's files); or the specific people with whom Ms. Kamage and Mr. Tracy consulted about the Commercial Success Argument.
- c. Defendants interposed numerous improper objections to Relator's Interrogatory Nos. 16-25, which objections Defendants served ten days late on March 25, 2024. (Relator served these interrogatories on February 15, 2024.) Defendants' objections were waived pursuant to Fed. R. Civ. P. 33(b)(4) & Committee Notes for Paragraph 4. Relator intends to meet and confer with Defendants and possibly file a discovery motion if the parties are unable to reach agreement. Relator wishes to focus on the following three interrogatories for possible discussion at the April 9 conference in an attempt to avoid motion practice:
 - i. Interrogatory No. 16. This interrogatory asks Defendants to describe the roles of each corporate entity that participated in bringing Zytiga to market. After asserting objections, Defendants respond that Johnson & Johnson is the parent company to the defendant Janssen entities, and that the "Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company." Relator believes this response is insufficient, including because it is non-responsive.
 - ii. Interrogatory No. 23. This interrogatory asks Defendants to describe the corporate relationships between and among Defendants and any affiliates involved with the sale of Zytiga. After asserting objections, Defendants answered that Johnson & Johnson is the parent company to the defendant Janssen entities. Relator believes this response is insufficient, including because it is non-responsive.

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- iii. Interrogatories No. 24-25. These interrogatories seek Defendants' legal and factual contentions relating to delay of generic entry (Interrogatory No. 24) and the materiality of Defendants' exclusion of generic competition upon the government's (or Plaintiff States') decision to pay or reimburse for Zytiga (Interrogatory No. 25). Defendants object that these interrogatories are premature and improper. Relator believes he is entitled to a substantive response to each of these interrogatories.
- 4. Defendants' refusal to provide Rule 30(b)(6) corporate representatives for certain topics requested by Relator. On March 2, 2024, Defendants provided their objections and responses to Relator's 30(b)(6) deposition notices for each of defendants Johnson & Johnson and its three Janssen subsidiaries. Relator intends to bring a discovery motion for many topics as to which Defendants arbitrarily narrowed in their responses while agreeing to produce a corporate designee. Relator wishes to raise the following topics for possible discussion at the April 9 conference to avoid motion practice because Defendants have refused to provide *any* witness relating to them:
 - a. Topic 12: The roles, rights, and responsibilities of each corporate entity that is a direct or indirect subsidiary of Johnson & Johnson, including the three Janssen subsidiaries, that participated in the research, development, manufacture, marketing, or sale of Zytiga.
 - b. Topic 13: The role, rights, and responsibilities of each Defendant relating to the '340 Application (for the allegedly fraudulent '438 Patent), the '440 Application (which was a discontinued application claiming the same inventions as the '340 Application), the '213 Patent (the original chemical compound patent), and the '438 Patent.
 - c. Topic 15: The acquisition, license, or transfer of any rights related to the '438 Patent.
 - d. Topic 16: Any actions taken by each defendant to enforce the '438 Patent, and any benefits derived by the defendant from enforcement of the '438 patent.
 - e. Topic 17: Any actions taken by each defendant related to the '340 Application and the '440 Application.
 - f. Topic 18: The sale of the authorized generic of Zytiga, including contracts, licenses, and control of the right to sell the authorized generic; and Defendants' goals and expectations with respect to the sale of an authorized generic.

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- g. Topic 19: Each Defendant's expectations, goals, and strategy with respect to launching a coated version of Zytiga.
- h. Topic 20: Each Defendant's expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga (the original was 250 mg).
- i. Topic 25: The negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga.
- j. Topic 26: The negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition.

5. Defendants' deficient responses to Relator's other Requests for Production of Documents. On March 15, 2024, Defendants served their objections and responses to Requests 88 through 100. Relator intends to meet and confer with Defendants and possibly file a discovery motion if the parties are unable to reach agreement. The following are some of the more important disputes:

- a. Request No. 88. This request seeks documents related to indemnity agreements between and among Defendants which would cover any liabilities from this action. Defendants have refused to search for any documents responsive to this Request.
- b. Request No. 89. This request seeks contracts, agreements, and licenses between Defendants and any affiliated companies related to Zytiga. After asserting objections, Defendants respond by agreeing to meet and confer and by pointing to several previously produced documents. Relator believes Defendants' response is not sufficient, because they have not agreed to produce all responsive documents.
- c. Request Nos. 90-93. These requests seek documents sufficient to show the role played by each individual Defendant in bringing Zytiga to market. Defendants respond only by agreeing to meet and confer. Defendants' responses are insufficient because they have not agreed to produce any responsive documents.
- d. Request No. 94-97. These requests seek electronic data files concerning sales of Zytiga. Relator will meet and confer with Defendants concerning certain deficiencies in prior data files provided by Defendants.
- e. Request No. 98. This request seeks documents sufficient to show the nature, authority, and purpose of various committees used by Defendants in connection with Zytiga, including the Zytiga Global Commercial Team and the Zytiga

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Compound Development Team. After asserting objections, Defendants respond by pointing to thousands of pages of previously produced documents, but those documents did not specifically address the authority and specific purposes of the committees or provide important details about their nature (including how they the committees were constituted and their members appointed). Defendants' response is not sufficient.

- f. Request No. 99. This request seeks documents relating to the appointment of personnel to various committees formed by Defendants in connection with Zytiga, including the Zytiga Global Commercial Team and the Zytiga Compound Development Team. Defendants merely offer to meet and confer without agreeing to produce any responsive documents.
- g. Request No. 100. This request seeks documents sufficient to show the valuation Defendants assigned to the '440 Application in connection with the acquisition of the predecessor entity of one of the Janssen subsidiary defendants. Defendants respond to this Request only by agreeing to meet and confer. Defendants have not agreed to produce any responsive documents.
6. Defendants' deficient responses to Relator's Requests for Admissions. On March 18, 2024, Defendants served their objections and responses. Relator believes most of Defendants' objections are meritless and intends to meet and confer with Defendants and possibly file a discovery motion if the parties are unable to reach agreement.
7. Relator intends to challenge Defendants' improper designation of Outside Counsel's Eyes Only for some of *Defendants'* documents (as opposed to those re-produced from generic competitors, which originally designated their documents as OCEO under the confidentiality order for the prior patent infringement litigation). ECF No. 329, at 4.
8. Relator requests that Defendants provide the last known addresses of certain former employees whom Relator seeks to depose, and for Defendants to cooperate in scheduling those depositions, or be precluded from introducing the testimony of such former employees at trial. While Relator has been able to locate and serve several former employees with subpoenas, Relator has not been able to locate or serve the following former employees of Defendants: Mary Todd, William Daly, Myra McCormack, and Michael Myers.
9. Defendants' deficient privilege log. Defendants have not logged privilege redactions in their privilege log, or identified which, if any, of such redactions relate to the submission of the allegedly fraudulent Commercial Success Argument that is at the heart of this litigation. Privilege assertions concerning this issue are the expected focus of Relator's anticipated motion challenging privilege.

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II. Defendants' Open Disputes

Defendants offer the following list of open discovery disputes complete with citations to the record identifying where each was previously briefed, as ordered by Judge Kiel. Defendants do not understand Judge Kiel's Order to invite the Parties to raise new disputes in circumvention of the ordinary discovery dispute process or to argue previously briefed arguments further. Defendants, of course, would be happy to elaborate on any of issues presented in this letter at Your Honor's request.

1. Depositions of apex witnesses, including J&J's current CEO. ECF 329 at 6 (discovery dispute letter forthcoming).
2. Relator's deficient responses to Defendants' Interrogatories.
 - a. Interrogatory No. 1, which asks Relator to identify all correspondence with the federal or any state governments in connection with the subject matter of this litigation (a statutory pre-requisite to filing an action under the False Claims Act and many state analogues). ECF 329 at 7; *see also* ECF 294 at 6. Relator has indicated he will provide an amended response, but has not committed to a deadline.
 - b. Interrogatory Nos. 17 and 18, which ask Relator to provide information on the processes and mechanisms through which he alleges that false claims were submitted to and processed by each federal and state government program at issue. ECF 316 at 22; ECF 329 at 7; *see also* ECF 294 at 6, FN2.
 - c. Interrogatory No. 11, which asks Relator to describe with particularity the false claims he alleges were submitted to the federal or state governments. ECF 316 at 22; *see also* ECF 294 at 6.
3. Relator's improper confidentiality designations on documents produced to Defendants pursuant to Judge Kiel's February 6, 2024 order, as well as improper privilege designations revealed by Relator's production of those documents. ECF 329 at 7.

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Respectfully yours,

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